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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/644,927 | 08/21/2003 | Norman J. Stern | 0135.03 | 8641 |

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| EXAMINER | |
|---|---|
| TONGUE, LAKIA J | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1645 | |

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/644,927 | STERN ET AL. | |
| | Examiner | Art Unit | |
| | Lakia J. Tongue | 1645 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on 9/16/05.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 35-37 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 35-37 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

Applicant's response filed on September 6, 2005 is acknowledged. Newly added claims 35-37 are pending and under consideration. Claims 1-34 have been canceled.

The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office Action.

### *Information Disclosure Statement*

1. Applicant has noted that it is unclear what the office wants applicants to do with respect to the information disclosure statement (IDS). The Examiner noted that there are references in the specification that do not appear on the IDS. The statement in the prior office action was solely intended to place Applicant on notice that only the references which appear on the IDS have been considered. In other words any of the references that have been disclosed in the instant specification but are not on the IDS have not been considered.

### *Objections Withdrawn*

2. In view of applicants response the objection to the specification is withdrawn.

### *Rejections Withdrawn*

3. In view of applicants response the rejection of claims 1, 2, 6 and 8, as it now pertains to new claim 36, under 35 U.S.C. 112, first paragraph on pages 7-12 is withdrawn.

4. In view of applicants response the rejection of claims 1, 2, 6 and 8, as it now pertains to new claims 36 and 37 under 35 U.S.C. 102(b) (Kanatani et al) on page 12 is withdrawn.

5. In view of applicants response the rejection of claims 1, 2, 6 and 8, as it now pertains to new claims 35-37 under 35 U.S.C. 102(b) (Robredo et al) on page 13 is withdrawn.

6. In view of applicants response the rejection of claims 1, 2, 6 and 8, as it now pertains to new claim 36, under 35 U.S.C. 102(b) (Ocana et al) on page 14 is withdrawn.

7. In view of applicants response the rejection of claims 1, 2, 6 and 8, as it now pertains to new claim 36, under 35 U.S.C. 102(b) (Collins et al) on page 14 is withdrawn.

***Rejections Maintained***

8. The rejection of claims 35 and 37under U.S.C. 102(b) (Kanatani et al) is maintained for the reasons set forth in the previous office action on page 12.

The rejection was on the ground that Kanatani et al disclose bacteriocin produced by *Lactobacillus Acidophilus,* which is active against closely related lactic acid bacteria (page 1061). The microorganisms disclosed in the instant specification are characterized by their anti-bacterial properties (page 6, 0007). The microorganism disclosed in the prior art is known to display antimicrobial activity (page 1061). Inherently, the bacteriocin produced by *Lactobacillus Acidophilus* would have identifying characteristics of the claimed bacterial strain.

Applicant urges that a) Kanatani et al fails to anticipate the instantly claimed invention, b) the amino acid sequence of Kanatani is not the same amino acid sequence of SEQ ID NO 1 and c) the reference is silent as to an isolated *Lactobacillus salivarius* having the identifying characteristics of NRRL B-30514.

Applicant's arguments are in regard to the rejection of Kanatani et al over a claim that is not being maintained. Therefore, the arguments are mute and are not being considered. It is the examiners position that claim 35 is drawn to an isolated bacteriocin produced by NRRL B-30514 wherein said bacteriocin is active against at least *Campylobacter jejuni, Salmonella enteritidis, Salmonella typhimurium, Salmonella choleraesuis, Escherichia coli, Klebsiella pneumoniae, Shigella dysenteriae, Yersinia enterocolitica,* and *Yersinia pseudotuberculos.* The claimed composition is the same as the composition of the prior art. The recitation of "produced by NRRL B-30514" as claimed in the invention is being viewed as a process limitation and must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. The preparation of an isolated bacteriocin does not impart novelty or unobviousness when the bacteriocin is taught by the prior art. Since the Patent Office does not have the facilities for examining and comparing applicants' bacteriocin with the bacteriocin of the prior art, the burden is on applicant to show a novel or unobvious distinction between the material structural and functional characteristics of the claimed isolated bacteriocin and the isolated bacteriocin of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Claim limitations such as "wherein the bacteriocin is active against" are being viewed as limitations of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the art. See *In re Casey,* 152 USPQ 235 (CCPA 1967) and *In re Otto,* 136 USPQ 458, 458.

Moreover, claim 37 is drawn to an isolated *Lactobacillus salivarius* NRRL B-30514. It is the examiner's position that the microorganism disclosed in the prior art is known to display antimicrobial activity (page 1061). Inherently, the bacteriocin produced by *Lactobacillus Acidophilus* would have identifying characteristics of the claimed bacterial strain.

9. The rejection of claims 35 and 37, under U.S.C. 102(b) (Ocana et al) is maintained for the reasons set forth in the previous office action on page 14.

The rejection was on the ground that Ocana et al disclose bacteriocins synthesized by bacteria having a narrow spectrum of activity, having the ability to inhibit a wide range gram-positive bacteria (page 5631). In addition Ocana et al disclose that *L. salivarius* was selected because of its ability to inhibit growth of microorganisms (page 5632). Inherently, the bacteriocin of the prior art produced by *Lactobacillus salivarius* would have the identifying characteristics of the claimed bacterial strain.

Applicant urges that a) the bacteriocin synthesized by the *L. salivarius* of the prior art does not anticipate the instantly claimed invention and b) the reference fails to anticipate the claims to an isolated *Lactobacillus salivarius* NRRL B-30514.

It is the examiners position that the claims are drawn to an isolated bacteriocin produced by NRRL B-30514 wherein said bacteriocin is active against at least *Campylobacter jejuni, Salmonella enteritidis, Salmonella typhimurium, Salmonella choleraesuis, Escherichia coli, Klebsiella pneumoniae, Shigella dysenteriae, Yersinia enterocolitica,* and *Yersinia pseudotuberculos.* Applicant has not provided any evidence via a side-by-side comparison to show that applicant's composition is not the same as that of the prior art. Thus, the claimed composition is the same as the composition of the prior art. Moreover, The recitation of "produced by NRRL B-30514" as claimed in the invention is being viewed as a process limitation and must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. The preparation of an isolated bacteriocin does not impart novelty or unobviousness when the bacteriocin is taught by the prior art. Since the Patent Office does not have the facilities for examining and comparing applicants' bacteriocin with the bacteriocin of the prior art, the burden is on applicant to show a novel or unobvious distinction between the material structural and functional characteristics of the claimed isolated bacteriocin and the isolated bacteriocin of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Claim limitations such as "wherein the bacteriocin is active against" are being viewed as limitations of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the

prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the art. See *In re Casey,* 152 USPQ 235 (CCPA 1967) and *In re Otto,* 136 USPQ 458, 458.

10. The rejection of claims 35 and 37, under U.S.C. 102(e) (Collins et al) is maintained for the reasons set forth in the previous office action on page 14.

The rejection was on the grounds that Collins et al discloses probiotic strains from *Lactobacillus salivarius.* Collins et al disclose the use of gram positive, catalase negative rod-shaped bacteria isolates (page 4, 0068). By all comparative data the strain of the prior art and the instantly claimed strain, absent evidence to the contrary, are the same. The strain of the prior art inherently anticipates the instantly claimed strain because by applicant's definition in the instant specification, the *Lactobacillus salivarius pvd32* strain is gram positive, catalase negative and pleomorphic rods (page 19, 0039). Additionally, the strain of the prior art would inherently have identifying characteristics of the claimed strain.

Applicant urges that a) the Collins et al reference fails to anticipate the presently claimed invention.

It is the examiners position that the claims are drawn to an isolated bacteriocin produced by NRRL B-30514 wherein said bacteriocin is active against at least *Campylobacter jejuni, Salmonella enteritidis, Salmonella typhimurium, Salmonella choleraesuis, Escherichia coli, Klebsiella pneumoniae, Shigella dysenteriae, Yersinia enterocolitica,* and *Yersinia pseudotuberculos.* Applicant has not provided any evidence via a side-by-side comparison to show that applicant's composition is not the same as that of the prior art. Thus, the claimed composition is the same as the composition of the prior art. Moreover, The recitation of "produced by NRRL B-30514" as claimed in the invention is being viewed as a process limitation and must result in a structural

difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. The preparation of an isolated bacteriocin does not impart novelty or unobviousness when the bacteriocin is taught by the prior art. Since the Patent Office does not have the facilities for examining and comparing applicants' bacteriocin with the bacteriocin of the prior art, the burden is on applicant to show a novel or unobvious distinction between the material structural and functional characteristics of the claimed isolated bacteriocin and the isolated bacteriocin of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Claim limitations such as "wherein the bacteriocin is active against" are being viewed as limitations of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the art. See *In re Casey,* 152 USPQ 235 (CCPA 1967) and *In re Otto,* 136 USPQ 458, 458.

Since the Office does not have the facilities for examining and comparing applicants' composition with the composition of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

## *New Grounds Necessitated by Amendment*

### *Claim Objections*

Claim 37 is objected to because of the following informalities: the word "newl" should be "new". Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 35 is rejected under U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention. *This is a written description rejection.*

Claim 35 is drawn to an isolated bacteriocin produced by NRRL B-30514 wherein said bacteriocin is active against at least *Campylobacter jejuni, Salmonella enteritidis, Salmonella typhimurium, Salmonella choleraesuis, Escherichia coli, Klebsiella pneumoniae, Shigella dysenteriae, Yersinia enterocolitica,* and *Yersinia pseudotuberculos.*

The specification broadly describes as part of the invention bacteriocins that are compounds produced by bacteria that have biologically active protein moiety and bactericidal action. The specification also broadly describes that characteristics may

include 1) a narrow inhibitory spectrum of activity centered about closely related species, 2) attachment to specific cell receptors and 3) plasmid-borne genetic determinants of bacteriocin production and of host cell bacteriocin immunity (pages 6-7). It is evident from these pages of the specification that applicant is describing their novel bacteriocin, however the above bacteriocin does not meet the written description provision of 35 USC 112, first paragraph. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116).

The skilled artisan cannot envision the detailed chemical structure of the encompassed bacteriocin and therefore conception cannot be achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481, 1483. In Fiddes v. Baird, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 35-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 35 recites in part "wherein the bacteriocin is active against". The examiner is unclear of what applicant intends by "active against".

Claim 36 is indefinite because it depends on canceled claim 1. Since claim 1 does not exist, the examiner unaware of the intended limitation.

Claim 37 recites "an isolated *Lactobacillus salivarius* NRRL B-30514". The examiner is unclear what the NRRL B-30514 refers to. Is this an accession number for the deposited strain or something else? Moreover, the function and structure of NRRL B-30514 is unclear.

Clarification is requested.

***Claim Rejections - 35 USC § 101***

11. The claimed invention is directed to non-statutory subject matter. Claim 36 is drawn to the bacteriocin of claim 1 having SEQ ID NO: 1. The claim reads on a product of nature. It is suggested that applicant amend the claim to recite isolated in order to overcome this rejection.

***Conclusion***

12. **No claims are allowed.**

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Stern et al (U.S. 2004/0220093 A1).

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakia J. Tongue whose telephone number is 571-272-2921. The examiner can normally be reached on Monday-Friday 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LJT

MARK NAVARRO
PRIMARY EXAMINER